NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 4. DEPARTMENT OF AGRICULTURE
PLANT SERVICES DIVISION

PREAMBLE

1. Sections Affected — **Rulemaking Action**
Table 1 of Article 1 — Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statute: A.R.S. §§ 3-107(A)(1)
Implementing statute: A.R.S. §§ 3-107, 3-233 (A)(7), 3-235, 3-906, 41-1074, 41-1075, 41-1076, and HB2044 of the 45th Legislature.

3. The effective date of the rules:
August 10, 2001

4. A list of all previous notices appearing in the Register addressing the adopted rule:
Notice of Rulemaking Docket Opening: 6 A.A.R. 1513, April 21, 2000

Notice of Proposed Rulemaking: 6 A.A.R. 3150, August 25, 2000

Notice of Supplemental Proposed Rulemaking: 6 A.A.R. 4315, November 17, 2000

Notice of Supplemental Proposed Rulemaking: 7 A.A.R. 1437, April 6, 2001

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:	Sherry Blatner, Rules Specialist
Address:	Department of Agriculture 1688 W. Adams, Room 235 Phoenix, AZ 85007
Telephone:	(602) 542-0962
Fax:	(602) 542-5420
E-mail:	sherry.blatner@agric.state.az.us

6. An explanation of the rule, including the agency's reasons for initiating the rule:
This rulemaking amends incorrect citations and data, adds licensing time-frames for seed dealers and seed labelers, extends the overall time-frame for phytosanitary field inspection, and deletes the time-frames for hay broker licenses to conform to a statutory change that eliminated this licensing requirement. The rulemaking amends the numbering scheme for Sections that were renumbered when the Department last updated the Native Plant rules in July 1999, and deletes the Native Plant educational license, which no longer exists in statute.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:
None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:
Not applicable

9. The summary of the economic, small business, and consumer impact:

A. *The Arizona Department of Agriculture*.

The Seed Dealer and Seed Labeler licensing time-frame (A.R.S. § 3-235) was previously established by internal policy at 7 days. It is now set at 14 days. All of these licenses are due during the same period of time, and the workload for these licenses has greatly increased. Therefore, a longer time-frame is needed to ensure that all requests are processed in a timely manner. For the fiscal year that ended June 30, 2000, 765 Seed Dealer licenses were issued, all within the required time-frame, but 673 of these licenses were issued in the month of June. For the fiscal year that ended June 30, 2000, 143 Seed Labeler licenses were issued, all within the required time-frame, but 139 of these licenses were issued in the month of June. The Department anticipates that with the promulgation of this rule package no future refunds or penalties will be incurred for noncompliance with the overall time-frame.

The increase in the phytosanitary field inspection time-frame should not have an economic impact on the Department, but will allow sufficient time to inspect the necessary crop stages that require the inspection.

B. *Political Subdivision.*

Political subdivisions of this state are not directly affected by the implementation and enforcement of this rulemaking.

C. *Businesses Directly Affected By the Rulemaking.*

Any businesses applying for a license will follow current procedures and no additional costs will occur. The increase in the phytosanitary field inspection time-frame will benefit businesses affected by this regulation as sufficient time to grow the applicable stages of crops will be allowed within the increased time-frame. Phytosanitary field inspections are necessary for growers shipping seed to foreign countries. It is a preliminary step in obtaining a federal phytosanitary certificate. The Division inspects the fields one to three times depending upon the crop. The proposed language provides an intangible benefit for businesses by identifying the time-frames in which the Division will approve or deny licenses.

D. *Private and public employment.*

Private and public employment is not directly affected by the implementation and enforcement of this rulemaking.

E. *Consumers and the Public.*

Consumers and the public are not directly affected by the implementation and enforcement of this rulemaking.

F. *State Revenues.*

This rulemaking may have a minor impact on state revenues. Continued departmental compliance with overall time-frames will avoid assessment of refunds and penalties.

The time-frames for the hay broker license were deleted. House Bill 2044, effective on August 9, 2001, repealed the statutory authority for the license, 3 A.A.C. 15, Article 5, Hay Agents, Brokers and Dealers. This rulemaking increases the time-frames for phytosanitary field inspection from 120 to 210 days, allowing inspection time of necessary crop stages. A math error in the time-frame table indicating an overall time-frame of 44 days for citrus fruit surface pests was corrected to 74 days. The native plant educational permit license was deleted in conformance with an earlier statutory change that eliminated this license. The title of the Salvage Restricted Native Plant Permit has not been changed in this rulemaking as had been initially proposed.

Minor clarifying changes were made in response to comments from Council staff.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The time-frames for the hay broker license were deleted. House Bill 2044, effective on August 9, 2001, repealed the statutory authority for the license, title 3, Chapter 15, Article 5, Hay Agents, Brokers and Dealers. this rulemaking increases the time-frames for phytosanitary field inspection from 120 to 210 days, allowing inspection time of necessary crop stages. A math error in the time-frame table indicating an overall time-frame of 44 days for citrus fruit surface pests was corrected to 74 days. the native plant educational permit license was deleted in conformance with an earlier statutory change that eliminated this license. The title of the Salvage Restricted Native Plant Permit has not been changed in this rulemaking as had been initially proposed.

11. A summary of the principal comments and the agency response to them:

No comments were received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules changes follows:

TITLE 3. AGRICULTURE

CHAPTER 4. DEPARTMENT OF AGRICULTURE
PLANT SERVICES DIVISION

ARTICLE 1. GENERAL PROVISIONS

Section
Table 1. Time-frames (Calendar Days)

ARTICLE 1. GENERAL PROVISIONS

TABLE 1. TIME-FRAMES
(Calendar Days)

License	Authority	Administrative Completeness Review	Response to Completion Request	Substantive Completeness Review	Response to Additional Information	Overall Time-frame
QUARANTINE						
Cotton Boll Weevil Pest	A.R.S. 3-201.01 R3-4-218	14	14	30	30	44
Citrus Fruit Surface Pest	A.R.S. 3-201.01 R3-4-219	14	14	60	30	~~44~~ 74
Citrus Nursery Stock Pests	A.R.S. 3-201.01 R3-4-220	14	14	30	30	44
Lettuce Mosaic Pest	A.R.S. 3-201.01 R3-4-233	14	14	30	30	44
Noxious Weeds Regulated and Restricted Prohibited	A.R.S. 3-201.01 R3-4-244 R3-4-245	14	14	30	30	44
Scale Insects Pests	A.R.S. 3-201.01 R3-4-226	14	14	30	30	44
Plum Curculio Apple Maggot	A.R.S. 3-201.01 R3-4-240	14	14	60	30	74
Colored Cotton	A.R.S. 3-205.02 R3-4-501	14	0	0	0	14
NURSERY						
Ozonium Root Rot Inspection Method of Growing Indicator Crop Planted On Applicant's Property Indicator Crop Planted In Surrounding Area	A.R.S. 3-201.01 A.R.S. 3-217 R3-4-303	 7 7 7	 14 14 14	 30 4 yrs 5 yrs	 14 14 14	 37 4yrs, 7 days 5yrs, 7 days
Other Certification Inspections Nursery Inspection	A.R.S. 3-201.01 A.R.S. 3-217	 30	 14	 1 yr	 14	 1 yr, 30 days
Phytosanitary Field Inspection ~~Phytosanitary Application~~	~~A.R.S. 3-201.01~~ ~~A.R.S. 3-217~~ A.R.S. 3-233(A)(7) R3-4-407	30	7	~~120~~ 210	7	~~150~~ 240
STANDARDIZATION						
Experimental Containers for Fruit and Vegetables	A.R.S. 3-487 R3-4-740	7	0	2	0	9
Experimental Containers for Citrus Fruit	A.R.S. 3-445 R3-4-814	7	0	2	0	9
Citrus Fruit Dealer, Packer or Shipper License	A.R.S. 3-449	10	14	10	14	20
Fruit and Vegetable Dealer, Packer or Shipper License	A.R.S. 3-492	10	14	10	14	20
ARIZONA NATIVE PLANTS						

Notice of Intent Confirmation Notice of Intent	A.R.S. 3-904 R3-4-602	7	14	7	14	14
Qualifications for Salvage Assessed Native Plant Permits Salvage Restricted Native Plant Permits Scientific ~~& Educational~~ Permits	A.R.S. 3-906 ~~R3-4-611~~ ~~R3-4-610~~ R3-4-608 R3-4-605	5 5 14	14 14 14	5 5 14	14 14 14	10 10 28
~~Blue Seal Permits~~ Movement Permits	A.R.S. 3-906 ~~R3-4-610~~ R3-4-607	5	14	5	14	10
Qualifications for Annual Permits For Harvest-Restricted Native Plants	A.R.S. 3-907 ~~R3-4-612~~ R3-4-608	5	14	5	14	10
SEED DEALERS AND LABELERS						
Seed Dealer	A.R.S. 3-235 R3-4-408	14	14	14	14	28
Seed Labeler	A.R.S. 3-235 R3-4-408	14	14	14	14	28
~~HAY BROKER~~						
~~Hay Broker License~~	~~A.R.S. 3-2712~~	~~5~~	~~5~~	~~5~~	~~5~~	~~10~~

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-23-604 Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1), (3), and (4) and (B)(3)

Implementing statutes: A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1932, 32-1961, 32-1962, 32-1963, and 32-1975

3. The effective date of the rules:

August 9, 2001

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 6 A.A.R. 3116, August 18, 2000

Notice of Proposed Rulemaking: 7 A.A.R. 952, February 23, 2001

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@qwest.net

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The Board's five-year rule review in September 1997 identified Section 604 for amendment. The rule removes language that mimics the federal Current Good Manufacturing Practice Regulations and then incorporates by reference the federal Current Good Manufacturing Practice Regulations. The Board already enforce federal law, so it is not necessary to have pages of rule that repeat almost verbatim the federal regulations. The rule is updated with language required by the current Administrative Procedure Act to produce a clear, concise, and understandable document.

Subsections (A) through (G) and (I) through (L) address areas specific to Arizona that are not addressed in the federal act, including permit application, notification, drug distribution, pharmacist-in-charge, recordkeeping and retention, inspections, nonresident manufacturer, and radiopharmaceuticals. Subsection (H) incorporates the federal Current Good Manufacturing Practice Regulations.

The Board believes that making these rules will benefit the public health and safety by establishing clear standards for resident manufacturer permits and the manufacturing and distribution of drugs in Arizona.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The cost to the Board of Pharmacy and the Secretary of State for writing and publishing the rule will be minimal. The rule will have no economic impact on drug manufacturers. The rule reduces the size of the Board's rule by repealing language that mimics the federal Current Good Manufacturing Practice Regulations and then incorporating by reference the federal Current Good Manufacturing Practice Regulations. The Board already enforces federal law, so this change will not impose anything new on manufacturers. The rule does not impose any additional costs on Arizona small business or consumers. The Board, drug manufacturers, and the public benefit from a rule that establishes clear standards for resident manufacturer permits and the manufacturing and distribution of drugs in Arizona.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

At the request of G.R.R.C. staff, the Board made various nonsubstantive style, format, grammar, and punctuation changes to the final rule to create a clear, concise, and understandable document in compliance with the Arizona Administrative Procedure Act.

11. A summary of the principal comments and the agency response to them:

There were no comments.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

21 CFR 210 through 211, published April 1, 2000, and no future amendments or editions, located at A.A.C. R4-23-604(H)

14. Was this rule previously approved as an emergency rule?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section

R4-23-604. ~~Manufacturers~~ Resident Drug Manufacturer

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-604. ~~Manufacturers~~ Resident Drug Manufacturer

A. ~~Permits:~~ Permit.

1. ~~No manufacturing of a drug shall be commenced or take place before a manufacturing permit has been approved, a final inspection approved by a drug inspector and the permit is issued to the permittee.~~ A person shall not manufacture, package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical without a current Board-issued drug manufacturer permit.

B. ~~2. The permittee applicant, manager and other employees at the Board's request shall furnish to the Board character references, fingerprints, education, experience and such other information as the Board may require. Records of employees~~

~~shall be kept for two years and furnished to the Board on request.~~ Application. To obtain a permit to operate a drug manufacturing firm in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:

1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
6. A copy of the drug list required by the FDA;
7. Plans or construction drawings showing facility size and security for the proposed business;
8. Applicant's and manager's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug manufacturer operation;
9. Pharmacist-in-charge's name, address, emergency telephone number, Arizona pharmacist license number, and expiration date;
10. The applicant's current FDA drug manufacturer or repackager registration number and expiration date;
11. Documentation of compliance with local zoning laws;
12. For an application submitted because of ownership change, the former owner's name and business name, if different;
13. Date signed, applicant's, corporate officer's, partner's, manager's, or pharmacist-in-charge's verified signature and title, and
14. Fee specified in R4-23-205.

~~3. The owner, responsible officers and/or manager and pharmacist in charge shall appear before the Board before the permit can be issued.~~

~~4. An application shall be completed on a form furnished by the Board, showing, among other things, the pharmacist in charge as required by A.R.S. §§ 32-1929 and 32-1961. The application shall be completed and in the Board's office at least 15 days before a Board meeting before it will be considered by The Board.~~

~~5. Applications shall list drugs that are to be manufactured. Drugs may be listed by categories unless more detail is required by the Board. If other drugs are desired to be manufactured at a later date, an amendment shall be made and no distribution of such additional drugs shall be made until the Board has been notified in writing.~~

C. Before issuing a drug manufacturer permit, the Board shall:

1. Receive and approve a completed permit application;
2. Interview the applicant and manager, if different from the applicant, and the pharmacist-in-charge at a Board meeting; and
3. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

D. Notification. A drug manufacturer permittee shall notify the Board of changes involving the drug list, ownership, address, telephone number, name of business, manager, or pharmacist-in-charge, including manager's or pharmacist-in-charge's telephone number.

E. Manufacturing and distribution.

1. A drug manufacturer permittee shall manufacture and distribute a drug only:
   a. To a pharmacy, drug manufacturer, and full-service or nonprescription drug wholesaler currently permitted by the Board;
   b. To a medical practitioner currently licensed as a medical practitioner as defined in A.R.S. § 32-1901; or
   c. To a properly permitted, registered, licensed, or certified person or firm of another jurisdiction; and
   d. Under the supervision of an Arizona Board-licensed pharmacist as required in A.R.S. § 32-1961. Manufacturing processes that require the supervision of a pharmacist include weighing, mixing, compounding, tableting, packaging, and labeling.
2. Before manufacturing and distributing a drug that is not listed on a drug manufacturer's permit application, the drug manufacturer permittee shall send to the Board office a written request to amend the permit application, including documentation of FDA approval to manufacture the drug not listed on the original permit application. If a request to amend a permit application includes the documentation required in this subsection, the Board or its designee shall approve the request to amend within 30 days of receipt.

F. ~~6. Manufacturing permits are~~ A drug manufacturer permit is subject to denial, suspension, probation, or revocation ~~for violation of state or federal laws and rules pertaining to drugs, including controlled substances~~ under A.R.S. § 32-1932.

G. ~~7. Manufacturing permittees shall comply with the registering and drug listing requirement of the Food and Drug Administration.~~ A drug manufacturer permittee shall:

1. Designate an Arizona Board-licensed pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall:

a. Communicate Board directives to the management, other pharmacists, interns, and other personnel of the drug manufacturer; and
b. Ensure compliance with all federal and state drug laws and rules by the drug manufacturer; and

2. Ensure that an Arizona Board-licensed pharmacist is present at the facility whenever a drug is manufactured, packaged, repackaged, labeled, or relabeled.

~~B~~**H.** ~~Finished pharmaceuticals; manufacturing practice:~~

1. ~~The criteria in R4-23-604(D)(1) through (J)(4) inclusive shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.~~
2. ~~The regulations in this part permit the use of precision automatic mechanical or electronic equipment in the production and control of drugs when adequate inspection and checking procedures are used to assure proper performance.~~ Current Good Manufacturing Practice. A drug manufacturer permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, published April 1, 2000, and no future amendments or editions, incorporated by reference and on file with the Board and the office of the Secretary of State.

~~C~~**I.** ~~Buildings:~~

1. ~~Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, labeling, or holding of a drug. The building shall:~~
   a. ~~Provide adequate space for:~~
      i. ~~Orderly placement of equipment and materials to minimize any risk of mix-ups between different drugs, drug components, in process materials, packaging materials, or labeling, and to minimize the possibility of contamination.~~
      ii. ~~The receipt, storage, and withholding from use of components pending sampling, identification, and testing prior to release by the materials approval unit for manufacturing or packaging.~~
      iii. ~~The holding of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.~~
      iv. ~~The storage of components, containers, packaging materials, and labeling.~~
      v. ~~Any manufacturing and processing operations performed.~~
      vi. ~~Any packaging or labeling operations.~~
      vii. ~~Storage of finished products.~~
      viii. ~~Control and production laboratory operations.~~
   b. ~~Provide adequate lighting, ventilation, and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, microbiological, dust, humidity, and temperature controls to:~~
      i. ~~Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage, or handling of another product.~~
      ii. ~~Minimize dissemination of microorganisms from one area to another.~~
      iii. ~~Provide suitable storage conditions for drug components, in-process materials, and finished drugs in conformance with stability information as derived under R4-23-604, subsection (I) paragraph (2).~~
   c. ~~Provide adequate locker facilities and hot- and cold-water washing facilities, including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.~~
   d. ~~Provide an adequate supply of potable water under continuous positive pressure in a plumbing system free from defects that could cause or contribute to contamination of any drug. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.~~
   e. ~~Provide suitable housing and space for the care of all laboratory animals.~~
   f. ~~Provide for safe and sanitary disposal of sewage, trash, and other refuse within and from the buildings and immediate premises.~~

Records. A drug manufacturer permittee shall:

1. Establish and implement written procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law;
2. Retain the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection (H) for at least two years after distribution of a drug or one year after the expiration date of a drug, whichever is longer; and
3. Make the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection (H) available within 48 hours for review by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).

~~D~~**J.** ~~Equipment:~~

1. ~~Equipment used for the manufacture, processing, packing, labeling, holding, testing, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose. The Equipment shall:~~
   a. ~~Be so constructed that all surfaces that come into contact with a drug product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.~~
   b. ~~Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact drug products so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.~~
   c. ~~Be constructed and installed to facilities adjustment, disassembly cleaning and maintenance to assure the reliability of control procedures, uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.~~
   d. ~~Be of suitable type, size, and accuracy for any testing, measuring, mixing, weighing, or other processing or storage operations.~~

Inspections. A drug manufacturer permittee shall make the drug manufacturer's facility available for inspection by the Board or its compliance officer under A.R.S. § 32-1904.

~~E~~**K.** ~~Personnel:~~

1. ~~The personnel responsible for directing the manufacture and control of the drug shall be adequate in number and back- ground of education, training, and experience, or combination thereof, to assure that the drug has the safety, identity, strength, quality, and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing or control operations they perform, the necessary training or experience, and adequate information concerning the reason for application of pertinent provisions of this part to their respective functions.~~
2. ~~Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drugs shall be excluded from direct contact with drug products until the condition is corrected. All employees shall be instructed to report to supervisory personnel any conditions that may have such an adverse effect on drug products.~~
3. ~~The pharmacist responsible for directing the manufacture and control of drugs shall furnish to the Board a completed fingerprint card. Fingerprint cards may also be required of other personnel at the Board's discretion.~~
4. ~~Character references shall be furnished by the pharmacist responsible for the manufacture and control of drugs and other personnel as requested by the Board. There shall be a notarized statement by such personnel concerning any and all charges of drug laws violations, past, present or pending, whether convicted or not.~~

Nonresident drug manufacturer. A nonresident drug manufacturer shall comply with the requirements of R4-23-607.

~~F.~~ ~~Production:~~

1. ~~Any and all manufacturing of drugs shall be under the supervision of an Arizona pharmacist as required in A.R.S. § 32-1961.~~
2. ~~Manufacturing processes required to be under the supervision of a pharmacist shall include, but not be limited to, such processes as weighing, mixing, compounding, tableting, packaging, and labeling.~~
3. ~~Components: All components and other materials used in the manufacture, processing, and packaging of drug products, and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary, and orderly manner. Adequate measures shall be taken to prevent mix-ups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a materials approval unit. Control of components shall include the following:~~
   a. ~~Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.~~
   b. ~~An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one or more tests to establish the specific identity.~~
   c. ~~Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.~~
   d. ~~Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate specifications.~~
   e. ~~Representative samples of components liable to microbiological contamination shall be subjected to microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.~~
   f. ~~Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity at time of use. This requires the following:~~
      i. ~~Approved components shall be handled and stored to guard against contaminating or being contaminated by~~

other drugs or components.

ii. Approved components shall be rotated in such a manner that the oldest stock is used first.

iii. Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

g. Appropriate records shall be maintained, including the following:

i. The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.

ii. Examinations and tests performed and rejected components and their disposition.

iii. An individual inventory and record for each component used in each batch of drug manufactured or processed.

h. An appropriately identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least two years after distribution of the last drug lot incorporating the component has been completed or one year after the expiration date of this last drug lot, whichever is longer.

4. Master production and control records, batch production and control records:

a. To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked, reconciled, dated, and signed or initialed by a second competent and responsible individual. The master production and control record shall include:

i. The name of the product, description of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dates by the person or persons responsible for approval of such labeling.

ii. The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of the total weight or measure of any dosage unit.

iii. A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; an accurate statement of the\ weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

iv. A description of the containers, closures, and packaging and finishing materials.

v. Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

b. The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two years after the batch distribution is complete or at least one year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include:

i. An accurate reproduction of the appropriate master formula record checked, dated, and signed or initialed by a competent and responsible individual.

ii. A record of each significant step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including: dates; individual major equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individual(s) actively performing and the individual(s) directly supervising or checking each significant step in the operation.

iii. A batch number that identifies all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

iv. A record of any investigation made according to R4-23-604(G)(5)(h).

5. Miscellaneous control procedures: Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the safety, identity, strength, quality, and purity they purport to possess:

a. Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or, if such steps in the processing are controlled by precision automatic, mechanical, or electronic equipment, their proper performance is adequately checked by one or more competent and responsible individuals. The written record of the significant steps in the process shall be identi-

fied by the individual performing these tests and by the individual charged with checking these steps. Such identification shall be recorded immediately following the completion of such steps.

b. All containers, lines, and equipment used during the production of a batch of a drug shall be properly identified at all times to accurately and completely indicate their contents and, when necessary, the stage of processing of the batch.

c. To minimize contamination and prevent mix-ups, equipment, utensils, and containers shall be thoroughly and appropriately cleaned and properly stored and have previous batch identification removed or obliterated between batches or at suitable intervals in continuous production operations.

d. Appropriate precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile or which by virtue of their intended use should be free from objectionable microorganisms.

i. Microbiological cultures and specimens to be discarded, and all other potentially infectious materials, shall be sterilized before disposal by either steam under pressure, dry heat, chemical disinfection, or in an incinerator approved by the air pollution control officer having jurisdiction.

e. Appropriate procedures shall be established to minimize the hazard of cross-contamination of any drugs while being manufactured or stored.

f. To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration times of tablets, and the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. In-process sampling shall be done at appropriate intervals using suitable equipment.

g. Representative samples of all dosage form drugs shall be tested to determine their conformancy with the specifications of the product before distribution.

h. Procedures shall be instituted whereby review and approval of all production and control records, including packaging and labeling, shall be made prior to the release or distribution of a batch. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has already been distributed. This investigation shall be undertaken by a competent and responsible individual and shall extend to other batches of the same drug and other drugs that may have been associated with the specific failure. A written record of the investigation shall be made and shall include the conclusions and follow-up.

i. Returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored, or shipped prior to or during their return, or the condition of the product, its container, carton, or labeling as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the drug, the returned goods shall be destroyed or subjected to adequate examination or testing to assure that the material meets all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of subparagraph (h) above.

G. Product containers and labeling:

1. Product containers and their components: Suitable specification, test methods, cleaning procedures, and when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use. Product containers and their components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the drug.

2. Packaging and labeling: Packaging and labeling operations shall be adequately controlled: to assure that only those drug products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mix-ups between drugs during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the drug; and to identify the finished product with a lot or control number that permits determination of the history of the manufacturer and control of the batch. An hour, day, or shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall:

a. Be separated (physically or spatially) from operations on other drugs in a manner adequate to avoid mix-ups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.

b. Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.

c. Include the following labeling controls:

i. The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.

ii. The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such a manner as to prevent mix-ups and provide proper identification.

iii. A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.

iv. Restriction of access to labels and package labeling to authorized personnel.

v. Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting, and handling during and after printing.

d. Provide strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of drug finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out according to R4-23-604(G)(5)(h).

e. Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met.

3. Any and all master labeling and package inserts, other printed materials and representations shall be filed with the Board before sale or distribution of the drug. All such material must comply with the federal laws as well as the Arizona laws. This is not intended to require approval by the Board before distribution.

H. Quality:

1. Laboratory controls: Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

a. The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of drug components, product containers, and their components subject to deterioration.

b. A reserve sample of all active ingredients as required by R4-23-604(G)(3).

c. The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly identified.

d. The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drug products. Such samples shall be adequately representative and properly identified.

e. Adequate provisions for checking the identity and strength of drug products for all active ingredients and for assuring:

i. Sterility of drugs purported to be sterile and free from objectionable microorganisms for those drugs which should be so by virtue of their intended use.

ii. The absence of pyrogens for those drugs purporting to be pyrogen free.

iii. Minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances.

iv. That the drug release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.

f. Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

g. A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least two years after the drug distribution has been completed or at least one year after the drug's expiration date, whichever is longer.

h. Provision for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least two years after distribution has been completed or one year after the drug's expiration date, whichever is longer.

~~i. Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.~~

~~j. Provision that firms which manufacture non-penicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such non-penicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.03 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.~~

~~2. Stability: There shall be assurance of the stability of finished drug products. This stability shall be:~~

~~a. Determined by reliable, meaningful, and specific test methods.~~

~~b. Determined on products in the same container-closure systems in which they are marketed.~~

~~c. Determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling), as well as on the reconstituted product.~~

~~d. Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates.~~

~~3. Expiration dating: To assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, and the label of all such drugs shall have suitable expiration dates which relate to stability tests performed on the product:~~

~~a. Expiration dates appearing on the drug labeling shall be justified by readily available data from stability studies such as described in R4-23-604(I)(2).~~

~~b. Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.~~

~~c. When the drug is marketed in the dry state for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product.~~

~~I.~~ ~~Distribution records:~~

~~1. Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug. Records shall be retained for at least two years after the distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.~~

~~2. To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed first whenever possible.~~

~~3. Records required for controlled substances shall be complied with.~~

~~4. Complaint files: Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with R4-23-604(G)(5)(h). The record of each investigation shall be maintained for at least two years after distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.~~

~~J.~~**L.** ~~Permit to manufacture radioactive pharmaceuticals:~~ Manufacturing radiopharmaceuticals.

~~1. Minimum requirements: The following minimum requirements, in addition to regulations pertaining to the manufacturing of other drugs, shall be met before~~ Before manufacturing a ~~radioactive pharmaceutical.~~ radiopharmaceutical, a drug manufacturer permittee shall:

1. ~~These requirements are in addition to~~ Comply with the regulatory requirements of the Arizona Radiation Regulatory Agency, ~~and~~ the U.S. Nuclear Regulatory Commission, ~~and~~ the ~~federal Food and Drug Administration regulations.~~ FDA, and this Section;
2. Be or employ an Arizona Board-licensed authorized nuclear pharmacist as specified in R4-23-681(A);
3. Comply with the requirements specified in R4-23-682(F)(1), (2), (3), and (5);
4. Hold a current Arizona Radiation Regulatory Agency Radioactive Materials License. If a drug manufacturer permittee who manufactures radiopharmaceuticals fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License, the permittee's drug manufacturer permit shall be immediately suspended pending a hearing by the Board;
5. Designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall:
   a. Communicate Board directives to the management, other pharmacists, interns, and other personnel of the drug manufacturer; and
   b. Ensure compliance with all federal and state drug laws and rules by the drug manufacturer;
6. Ensure that an authorized nuclear pharmacist:
   a. Directly supervises all personnel who perform tasks in the manufacture and distribution of radiopharmaceuticals; and

b. Is present at the facility whenever a radiopharmaceutical is manufactured, packaged, repackaged, labeled, relabeled, or distributed.

~~a. Space: The radiopharmaceutical manufacturing or preparation area, separate and apart from other areas, shall be an undivided area of not less than 300 square feet with an additional minimum of 80 square feet for the hot lab and storage area. The area shall contain adequate sink with hot and cold water facilities.~~

~~b. Minimum equipment and accessory standards:~~

~~i. Fume hood, approved by the Arizona Radiation Regulatory Agency,~~

~~ii. Laminar flow hood,~~

~~iii. Dose calibrator,~~

~~iv. Refrigerator,~~

~~v. Electronic balance,~~

~~vi. Spectrophotometer,~~

~~vii. Drawing station,~~

~~viii. Radiochromatic strip scanner, well scintillation counter, scaler and multichannel analyzer,~~

~~ix. Microscope,~~

~~x. Incubator oven,~~

~~xi. Autoclave,~~

~~xii. Pyrogen oven,~~

~~xiii. Other equipment necessary for the radiopharmaceutical quality control for products manufactured as required by the Arizona Radiation Regulatory Agency.~~

~~c. Glassware:~~

~~i. 6 beakers 50 ml,~~

~~ii. 6 beakers 150 ml,~~

~~iii. 2 beakers 500 ml,~~

~~iv. 4 volumetric flasks 50 ml,~~

~~v. 12 volumetric flasks 100 ml,~~

~~vi. 4 graduated cylinders 10 ml.~~

~~d. Supplies:~~

~~i. Disposable syringes 1, 3 and 5 cc,~~

~~ii. Multidose vials 10, 20 and 30 cc,~~

~~iii. Disposable alcohol swabs and gloves,~~

~~iv. Appropriate labels for radioactive drugs,~~

~~v. Other supplies necessary for drugs to be manufactured.~~

~~e. Reference books:~~

~~i. A.R.S. § 30-651 through 30-687 pertaining to the Arizona Radiation Regulatory Agency,~~

~~ii. Rules of the Arizona Radiation Regulatory Agency,~~

~~iii. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,~~

~~iv. United States Pharmacopeia and National Formulary, or Remington, or United States Dispensatory, the latest edition and supplements,~~

~~v. American Hospital Formulary Service,~~

~~vi. Arizona Pharmacy Act and regulations,~~

~~vii. Arizona Narcotic Act,~~

~~viii. Radiological Health Handbook.~~

~~**K.** Education and experience: In addition to the education and experience required by the Arizona Radiation Regulatory Agency, a permittee to manufacture radioactive pharmaceuticals shall present to the Board certification from an accredited college of pharmacy that the pharmacist in charge for the manufacturing of radioactive pharmaceuticals has completed courses of 90 or more clock hours of formal academic training in nuclear pharmacy and certification he has completed a minimum of three months on-the-job training under a program approved by the Board and further shall pass an examination given by the Board on good manufacturing practices.~~

~~**L.** Food and Drug Administration registration: A manufacturer of radioactive pharmaceuticals shall register with the federal Food and Drug Administration.~~

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-23-606	Amend
R4-23-607	Amend
R4-23-613	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1) and (2)

Implementing statutes: A.R.S. §§ 32-1904(B)(5), 32-1929, 32-1930, 32-1931, 32-1932, 32-1934, and 32-1963

3. The effective date of the rules:

August 9, 2001

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 6 A.A.R. 4759, December 22, 2000

Notice of Proposed Rulemaking: 7 A.A.R. 962, February 23, 2001

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@qwest.net

6. An explanation of the rule, including the agency's reasons for initiating the rule:

During the five-year rule review in 1997, the Board staff noted that Section 606 should be revised to bring the terminology into conformity with state statute. Section 606 was originally a part of a rulemaking that included Sections 402 and 601. Because of extensive format and style changes recommended by GRRC staff, Section 606 was pulled from that rulemaking package and noticed as a separate rulemaking package. Some of the changes recommended for Section 606 ended up in a new Section 613. Section 607 is amended to include nonresident pharmacy permit requirements. The nonresident pharmacy permit requirements were inadvertently left out of Section 607 when it was amended on November 13, 2000. The rule includes necessary style, format, and grammar changes to provide a clear, concise, and understandable document.

The 1999 Legislature passed H.B. 2448 (Precursor Chemical bill) requiring the Board to issue permits to anyone (resident or nonresident) who distributes precursor chemicals such as ephedrine, pseudoephedrine, and phenylpropanolamine. These chemicals are active ingredients in common over-the-counter products sold for treatment of flu, colds, and weight loss. These changes prompted the Board to require a Board-issued permit for anyone (resident or nonresident) who distributes any drug in or into Arizona. In a final rulemaking filed with the Secretary of State and effective on November 13, 2000, the Board amended Section 607 to establish the requirements for nonresident manufacturer, full service and nonprescription drug wholesaler, and nonprescription drug retailer permits. Because nonresident pharmacy permits were inadvertently left out of the previous rulemaking, this rule amends Section 607 to establish the requirements for nonresident pharmacy permits.

The language in Section 606 receives numerous changes in style, format, punctuation, and grammar to comply with the statutory requirements of the Administrative Procedure Act and rules of the Secretary of State and Governor's Regulatory Review Council. Subsections (A) through (G) are amended to establish requirements related to permits, applications, notification, nonprescription drug sales, change of ownership, relocation or remodel, and changes of corporate officers. Subsections (H) through (L) are repealed.

G.R.R.C. staff recommended establishing a new Section to incorporate the procedure for closing a pharmacy previously contained in R4-23-606(L). New Section 613 includes new language establishing the procedure for discontinuing a pharmacy.

The Board believes that making these rules will benefit the public health and safety by establishing clear standards for resident and nonresident pharmacy permits and the distribution of drugs in and into Arizona.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The rule will have a direct economic impact on nonresident pharmacies that ship drugs into Arizona. The permit fee for a resident or nonresident pharmacy is $300 biennially. In the 1999 House Bill 2448, the Arizona Legislature required that the Board issue a permit to any person who ships a precursor chemical (nonprescription drug) into the state. To accomplish this on November 13, 2000, the Board amended R4-23-601 to eliminate the exemption from registration for nonresident firms shipping prescription-only or nonprescription drugs into Arizona. This means the Board must issue a permit to any firm shipping any drug into Arizona. The cost to the Board to permit nonresident pharmacies could be substantial. These costs include identifying, contacting, and educating nonresident pharmacies regarding the new requirements, issuing and renewing permits for affected nonresident pharmacies, investigation of complaints against nonresident pharmacies, and enforcement of statutes and rules. The cost to the Board of Pharmacy and the Secretary of State for writing and publishing the rule will be minimal. The rule will have no economic impact on resident pharmacies. The rule does not impose any additional costs on Arizona small business or consumers.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

At the request of G.R.R.C. staff, the Board made minor grammar, style, format, and punctuation changes. The Board decided to take out the requirement in R4-23-606(B)(1)(n), R4-23-607(C)(1)(d), and R4-23-607(F) that a nonresident pharmacy's pharmacist-in-charge have an Arizona pharmacist license. Simply requiring a pharmacist who will not practice in Arizona to get an Arizona pharmacist license will not increase public safety, but merely increase Board revenue. The Board staff discovered that only four states of the 30 plus states that issue nonresident pharmacy permits require that the pharmacist-in-charge have a pharmacist license issued by the nonresident state. The Board chose to go with the majority and not seek nonresident pharmacist-in-charge licensure, because each nonresident pharmacy is already required by their domicile state to have a licensed pharmacist-in-charge. This is a nonsubstantive change because it reduces the burden on a permittee. Subsection R4-23-607(G) is renumbered to R4-23-607(F).

11. A summary of the principal comments and the agency response to them:

There were no comments.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously approved as an emergency rule?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section

R4-23-606. Pharmacy Permit, Community, Hospital, and Limited Service

R4-23-607. Nonresident Permits

R4-23-613. Procedure for Discontinuing a Pharmacy

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-606. Pharmacy Permit, Community, Hospital, and Limited Service

A. ~~Pharmacy permit in general: No person may operate a pharmacy before the Board has approved the application, inspected the premises, and issued a permit.~~ Permit. A person shall not operate a pharmacy in Arizona without a current Board-issued pharmacy permit.

B. ~~Qualifications for applicants for pharmacy permit: Any person, including firm or corporation, applying for a pharmacy permit shall submit to the Board satisfactory proof that the owner, and manager has not been convicted or not then under any charges of felony, or of an offense involving moral turpitude, or of the laws pertaining to drugs, devices and poisons. A non-pharmacist manager shall be requested to appear before the Board with his pharmacist-in-charge before approval of the permit. Fingerprints shall be furnished at request of Board.~~ Application.

1. To obtain a permit to operate a new pharmacy or change ownership, relocate, or remodel an existing pharmacy in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:
   a. The type of pharmacy;
   b. Business name, address, mailing address, if different, telephone number, and facsimile number;
   c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
   d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
   e. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
   f. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
   g. Whether the owner, any officer, or partner is a medical practitioner;
   h. Name and telephone number of individual to contact before opening;
   i. If applying for a hospital pharmacy permit, the hospital's Department of Health Services license number, number of beds, and manager's or administrator's name;
   j. Planned opening, change of ownership, relocation, or remodel date;
   k. Plans or construction drawings showing pharmacy size and security for the proposed business;
   l. Documentation of compliance with local zoning laws;
   m. Lease agreement and a disclosure statement indicating whether a medical practitioner receives income from the lease;
   n. Pharmacist-in-charge's name;
   o. For an application submitted because of ownership change, the former pharmacy's name, address, owner's name, and permit number;
   p. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, or pharmacist-in-charge's verified signature and title; and
   q. Fee specified in R4-23-205.
2. Before issuing a pharmacy permit, the Board shall:
   a. Receive and approve a completed permit application; and
   b. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.
3. Before issuing a pharmacy permit, the Board may interview the applicant and the pharmacist-in-charge, if different from the applicant, at a Board meeting based on the need for additional information.

C. ~~Pharmacy permit not issued under certain conditions: A pharmacy permit shall not be issued whereby a medical practitioner may receive compensation for his prescription orders whether directly or indirectly. This shall not include instances where sporadic prescription orders of a medical practitioner may be filled.~~ Notification. A pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, pharmacy area, ownership, address, telephone number, name of business, pharmacist-in-charge, or staff pharmacist.

D. ~~Lease may be required: A pharmacy permittee or an applicant for a pharmacy permit may be required to reveal their lease to the Board upon request to prove that a medical practitioner is not receiving more than the prevailing rent which might be considered a rebate.~~ If any nonprescription drugs are sold outside the pharmacy area when the pharmacy area is closed, the pharmacy permittee shall ensure that the business has a current, Board-issued nonprescription drug permit as required in Sections R4-23-602 and R4-23-603.

E. ~~Approval of plans: The pharmacy area, waiting area, storerooms, restrooms and all partitions, doors, windows, and fixtures pertaining thereto shall be indicated on floor plans showing appropriate elevations and shall be submitted to the Board at the time the application for a new pharmacy is filed or prior to remodeling. Such plans shall be submitted prior to proceeding with new construction. Before a pharmacy permit shall be issued the plans submitted must meet the approval of the Board.~~ Change of ownership. Before any change of ownership occurs, a prospective owner shall submit the application packet described under subsection R4-23-606(B), except for changes of stock ownership of less than 30% of the vot-

ing stock of a corporation or an existing and continuing corporation that is actively traded on any securities market or over-the-counter market.

F. ~~Patent or proprietary permit required outside pharmacy area: If any drugs are sold outside the pharmacy area when the pharmacist is not in attendance, a patent or proprietary medicine permit or a general dealer's permit shall be required.~~ Before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit the application packet described under subsection R4-23-606(B), except a fee is not required. The new or remodeled facility shall pass a final inspection by a Board compliance officer before operations begin.

G. ~~New pharmacies: Whenever it is desired to open a new pharmacy, it shall be necessary for the ownership to apply in advance to the Board on a form prescribed and furnished by the Board. The application shall be accompanied by a biennial fee which shall be collected in accordance with the provisions of A.R.S. § 32-1931. Renewals will not be granted for a period less than 24 months. Fees are not refunded under any circumstances.~~ A pharmacy permittee shall submit the application packet described under subsection R4-23-606(B) for any change of officers in a corporation, except a fee and final inspection are not required.

H. ~~Change of ownership: Whenever there are any changes in ownership in a pharmacy, except for changes due to death of an individual owner or of a partner, as in subsection (J) below, it shall be necessary for the new ownership to apply in advance of the change on a form prescribed and furnished by the Board, the same as for a new pharmacy, accompanied by a biennial fee as required by subsection (G) of this Section for a new pharmacy. It shall be considered a change of ownership if there is a change of stock ownership involving 30 percent or more of the voting stock of a corporation, except in an existing and continuing corporation which is actively traded on any securities market or in any over-the-counter market. Fees are not refunded under any circumstance.~~

I. ~~Change of officers in a corporation: The Board shall be notified whenever there is a change of officers in a corporation owning a pharmacy permit, listing the new officers, and their home addresses, and additional information if required.~~

J. ~~Change due to death of owner or partner: If there is a death of an individual owner or of a partner and it is desired to continue the operation of the pharmacy, the estate or heirs or a partnership consisting of the estate or heirs of the deceased partner and the remaining partners must file an application upon a form prescribed and furnished by the Board, for which there shall be no fee, indicating the changes which have taken place and supplying any other requested information.~~

K. ~~Change of location: Whenever a pharmacy is to be moved to a new location it shall be necessary to apply on a form prescribed and furnished by the Board, indicating the new location and submitting plans for approval similarly to application for a new pharmacy, except there shall be no fee. The new premises shall be inspected before beginning operations.~~

L. ~~Procedure for closing a pharmacy:~~

1. ~~Ten days prior to closing, a written notice shall be sent to the Board office and to the Drug Enforcement Administration (D.E.A.). The notice shall contain, as a minimum, the following information:~~
   a. ~~Name, address, pharmacy permit number, and D.E.A. registration number of the pharmacy discontinuing business.~~
   b. ~~Name, address, pharmacy permit number (if applicable), and D.E.A. registration number of the licensee or registrant to whom the prescription drugs will be transferred.~~
   c. ~~The name and address of the location at which the records of the purchase and disbursement of controlled substances and prescription drugs will be kept. These records must be retained for a minimum of three years from the date of the last entry.~~
   d. ~~The name and address of the location at which the prescription files, patient and/or family records will be kept.~~
   e. ~~The proposed date of discontinuing business.~~
2. ~~All drug signs and symbols must be removed from both the inside and outside of the premises.~~
3. ~~All state permits and certificates of registration shall be returned to the Board office. D.E.A. registration certificates and unused D.E.A. Schedule II order forms should be returned to the D.E.A. Regional Office in Phoenix.~~
4. ~~No one except the pharmacist-in-charge of the pharmacy discontinuing business shall have access to the prescription drugs until they are transferred to the new owner. When the pharmacy has been closed and the pharmacy permit has been surrendered, the prescription drugs must be removed from the premises.~~
5. ~~Drugs shall be transferred in accordance with the following procedures:~~
   a. ~~An inventory of all controlled drugs being transferred shall be taken as of the close of business. A copy shall be used to adjust the purchaser's inventory.~~
   b. ~~The inventory of all Schedule II drugs shall be an accurate count. All other controlled drugs may be estimated unless quantities exceed 1,000 each, in which case an accurate count shall be made. A D.E.A. form 222 must be provided by the purchaser for Schedule II drugs.~~
   c. ~~The inventory shall list the name, strength, dosage form and quantity of all controlled drugs transferred.~~
   d. ~~Drugs to be destroyed shall be transferred in the same manner as all other drugs. The new owner shall then contact the Board office requesting an inspection for the purpose of drug destruction.~~
   e. ~~A copy of the inventory shall be included by the Board in the records of both the pharmacy discontinuing business and the new owner.~~

~~6. Statistical information pertaining to prescriptions, drug records, and other information pertaining to the pharmacy discontinuing business shall be furnished to the Board upon request by the individuals referred to in R4-23-606(L)(1)(c) and (d).~~

R4-23-607. Nonresident Permits

A. Permit. A person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
1. A current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit; and
2. A current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides.

B. Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permit, a person shall submit a completed application, on a form furnished by the Board, that includes:
1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. ~~Documentation of compliance with local zoning laws~~ A copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2);
6. For an application submitted because of ownership change, the former owner's name and business name, if different;
7. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or responsible person's verified signature and title, and
8. Fee specified in R4-23-205.

C. In addition to the requirements of subsection (B), the following information is required:
1. Nonresident pharmacy.
   a. The type of pharmacy;
   b. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
   c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides.;
   d. Pharmacist-in-charge's name and telephone number; and
   e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number; and

~~1.~~2. Nonresident manufacturer.
   a. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
   b. A copy of the drug list required by the FDA;
   ~~c. Plans or construction drawings showing facility size and security adequate for the proposed business;~~
   ~~d.~~c. Manager's or responsible person's name, address, and emergency telephone number; and
   ~~e.~~d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and

~~2.~~3. Nonresident full-service or nonprescription drug wholesaler.
   a. The type of drug wholesale permit;
   b. Whether the owner, any officer, or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
   c. The ~~type~~ types of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
   ~~d. Plans or construction drawings showing facility size and security adequate for the proposed business;~~
   ~~e.~~d. Manager's or responsible person's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug wholesale operation; and

~~3.~~4. Nonresident nonprescription drug retailer.
   a. Whether applying for Category I or Category II permit;
   b. Date business started or planned opening date; and

c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

D. Notification.

1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.

~~1.~~2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

~~2.~~3. Nonresident drug wholesaler. A nonresident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the ~~type~~ types of drugs sold or distributed, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

~~3.~~4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

E. Drug Sales.

1. Nonresident pharmacy. A nonresident pharmacy permittee shall not:
   a. Sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:
      i. A pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board;
      ii. A medical practitioner currently licensed under A.R.S. Title 32; or
      iii. An Arizona resident upon receipt of a valid prescription order for the resident; and
   b. Sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:
      i. A pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;
      ii. A medical practitioner currently licensed under A.R.S. Title 32; or
      iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer.

~~1.~~2. Nonresident manufacturer. A nonresident manufacturer permittee shall not:
   a. Sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except, a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32; and
   b. Sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32.

~~2.~~3. Nonresident full-service drug wholesaler. A nonresident full-service drug wholesale permittee shall not:
   a. Sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32; and
   b. Sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32.

~~3.~~4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32.

~~4.~~5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
   a. Sell, distribute, give away, or dispose of, a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
   b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical; ~~and~~ or
   c. Sell, distribute, give away, or dispose of, any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.

F. When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.

R4-23-613. Procedure for Discontinuing a Pharmacy

A. A pharmacy permittee or pharmacist-in-charge shall provide written notice to the Board and the Drug Enforcement Administration (D.E.A.) at least 10 days before discontinuing operation of the pharmacy. The notice shall contain the following information:
1. Name, address, pharmacy permit number, and D.E.A. registration number of the pharmacy discontinuing business;
2. Name, address, pharmacy permit number (if applicable), and D.E.A. registration number of the licensee, permittee, or registrant to whom the prescription-only drugs and controlled substances will be sold or transferred;
3. Name and address of the location where the discontinuing pharmacy's records of purchase and disbursement of controlled substances and prescription-only drugs will be kept and the person responsible for the records. These records shall be kept for a minimum of three years from the last transaction date.
4. Name and address of the location where the discontinuing pharmacy's prescription files and patient profiles will be kept and the person responsible for the files and profiles. These records shall be kept for a minimum of three years from the date the last original or refill prescription was dispensed; and
5. The proposed date of discontinuing business operations.

B. The pharmacy permittee shall ensure that all pharmacy signs and symbols are removed from both the inside and outside of the premises.

C. The pharmacy permittee or pharmacist-in-charge shall ensure that all state permits and certificates of registration are returned to the Board office and that D.E.A. registration certificates and unused D.E.A. Schedule II order forms are returned to the D.E.A. Regional Office in Phoenix.

D. The pharmacist-in-charge of the pharmacy discontinuing business shall ensure that:
1. Only a pharmacist has access to the prescription-only drugs and controlled substances until they are transferred to the licensee, permittee, or registrant listed in subsection (A)(2);
2. All prescription-only drugs and controlled substances are removed from the premises on or before the date the pharmacy is discontinued; and
3. All controlled substances are transferred as follows:
   a. Take an inventory of all controlled substances that are transferred using the procedures in R4-23-1003;
   b. Include a copy of the inventory with the controlled substances that are transferred;
   c. Keep the original of the inventory with the discontinued pharmacy's records of drug purchase and disbursement for a minimum of three years from the date the pharmacy is discontinued;
   d. Use a D.E.A. form 222 to transfer any Schedule II controlled substances; and
   e. Transfer controlled substances that need destruction in the same manner as all other controlled substances.

E. Upon receipt of outdated or damaged controlled substances from a discontinued pharmacy, the licensee, permittee, or registrant described in subsection (A)(2) shall contact a D.E.A. registered reverse distributor for proper destruction of outdated or damaged controlled substances. If there are controlled substances a reverse distributor will not accept, the licensee, permittee, or registrant shall then contact the Board office and request an inspection for the purpose of drug destruction.

F. During the three year record retention period, the person described in subsection (A)(3) or (4) shall provide to the Board upon its request a discontinued pharmacy's records of the purchase and disbursement of controlled substances and prescription-only drugs, prescription files, and patient profiles.

NOTICE OF FINAL RULEMAKING

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION TITLE, REGISTRATION, AND DRIVER LICENSES

PREAMBLE

1. Sections Affected:	**Rulemaking Action:**
R17-4-504	Repeal
R17-4-505	Repeal
R17-4-511	Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 28-366

Implementing statute: R17-4-504 implements the former A.R.S. § 28-692.01 and Laws 1990, Ch. 375, § 20. R17-4-505 implements the former A.R.S. §§ 28-692.01 and 28-694. R17-4-511 does not have a specific implementing statute. A.R.S. Title 28 was repealed and completely rewritten during the 1995 and 1996 Legislative sessions. As a result, the implementing statutes listed above do not have exact analogues in the current A.R.S. Title 28. However, Laws 1996, Ch. 76, § 309 provides that administrative rules made under the old laws remain in force until amended by the Department.

3. The effective date of the rules:

August 10, 2001

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 1263, March 16, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 1364, March 30, 2001

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Bill Bishop, Rules Analyst

Address: Arizona Department of Transportation
Administrative Rules Unit, Mail Drop 507M
3737 North Seventh Street, Suite 160
Phoenix, Arizona 85014-5017

Telephone: (602) 712-8449

Fax: (602) 241-1624

E-mail: bjbishop@dot.state.az.us

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters: www.dot.state.az.us/about/rules.

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The Department reviewed these rules as it committed to do in a five-year rule review report approved by the Governor's Regulatory Review Council on June 6, 2000 (F-00-0603).

R17-4-504(A) was written to implement A.R.S. § 28-692.01 which related to driving under the influence. In the years since the rule was adopted, the law was renumbered as A.R.S. § 28-1381 and its provisions were rewritten by the Legislature to include much more specificity. This law contains enough detail to make R17-4-504(A) therefore unnecessary.

R17-4-504(B) implements Laws 1990, Ch. 375, § 20 which provides for removal of points from driver's licenses if a person followed the procedure in the former A.R.S. § 28-692.01(E). Even though Laws 1990, Ch. 375, § 20 was never repealed, the section of the statutes to which it points was repealed. Section 692.01(E) was renumbered to (D) by Laws 1992, Ch. 330, § 23. The language in this new section (D) was then completely deleted by Laws 1993, Ch. 223, § 7. R17-4-504(B) is therefore unnecessary.

R17-4-505 was written to implement the alternate suspension procedures provided in the former A.R.S. § 28-694. This statute was subsequently renumbered as A.R.S. § 28-3165 and its provisions were rewritten and expanded. The statute now contains enough detail to make this rule unnecessary.

R17-4-511 gives procedures for compiling and indexing of records that the Motor Vehicle Division receives so that they may be stored electronically. This rule governs only internal procedures of the Department and does not affect the public. This rule is not needed.

7. A reference to any study that the agency relied on its evaluation or justification for the rule, and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

This rulemaking will decrease monitoring and recordkeeping and is therefore exempt from the requirement to provide the impact statement as provided in A.R.S. § 41-1055(D)(3).

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Not applicable

11. A summary of the principal comments and the agency response to them:
The Department did not receive any comments.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
None

13. Incorporations by reference and their location in the rules:
None

14. Was this rule previously adopted as an emergency rule?
No

15. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION TITLE, REGISTRATION, AND DRIVER LICENSES

ARTICLE 5. DRIVER LICENSES

Section
R17-4-504. ~~Notification for purposes of 30/60-day driving privileges suspension/restriction or driving record points removal~~ Repealed
R17-4-505. ~~Notification for alternate suspension provisions under Admin Per Se~~ Repealed
R17-4-511. ~~Computer storage of driver license applications, changes of address and records of conviction; original records disposal~~ Repealed

R17-4-504. ~~Notification for purposes of 30/60-day driving privileges suspension/restriction or driving record points removal~~ Repealed

~~**A.** Notification for purposes of A.R.S. § 28-692.01(J) shall be in the form of:~~
~~1. An affidavit from the arresting agency which specifies that the named person did not cause serious physical injury as set forth in A.R.S. § 28-692.01(C)(2) and a determination by the Motor Vehicle Division that the person meets the requirement of A.R.S. § 28-692.01(C)(1); or~~
~~2. An abstract or judgment order from the sentencing court which specifies that the named person was sentenced pursuant to A.R.S. § 28-692.01(D) or (E).~~

~~**B.** Notification for purposes of A.R.S. Laws 1990, Chapter 375, § 20 shall be in the form of a certified court record received by the Motor Vehicle Division, which record specifies that the named person has successfully completed the probation imposed pursuant to A.R.S. § 28-692.01(E).~~

R17-4-505. ~~Notification for alternate suspension provisions under Admin Per Se~~ Repealed

~~**A.** Definitions: "Admin Per Se" means the civil action and sanctions pursuant to A.R.S. § 28-694.~~
~~**B.** The Motor Vehicle Division, Arizona Department of Transportation shall impose an alternate suspension of a 30-day license suspension followed by a 60-day restricted license upon receipt of notification.~~
~~**C.** Notification shall indicate the arrestee meets the alternate suspension provisions pursuant to A.R.S. § 28-692.01(C). Notification shall be in the form of:~~
~~1. An affidavit from the arresting agency, or~~
~~2. An abstract or judgment order from the sentencing court which specified the sentence is under the alternate suspension criteria.~~
~~**D.** The Division shall adjust all records to reflect the suspension set forth.~~

R17-4-511. ~~Computer storage of driver license applications, changes of address and records of conviction; original records disposal~~ Repealed

~~**A.** Driver license applications and changes of address:~~
~~1. Whenever a person applies to the Department for:~~
~~a. An instruction permit pursuant to A.R.S. § 28-415 or 28-417.01;~~
~~b. An operators or chauffeurs license under the provisions of A.R.S. § 28-416;~~
~~c. A license for identification purposes only pursuant to A.R.S. § 28-421.01;~~
~~d. A license to drive a motorcycle or motor driven cycle, or~~
~~e. A duplicate license pursuant to A.R.S. § 28-425; the information contained on the application which is required by the respective statute allowing the application shall be indexed and compiled on the Department's computer in a manner which will allow retrieval and disclosure of statutorily required information.~~

~~2. Whenever a person notifies the Department of a change of address or change of name as required by A.R.S. § 28-427, this information shall be placed on the Department's computer in such a manner as to allow retrieval and disclosure of the new information and in place of that shown on the original application.~~

~~**B.** Records of conviction:~~

~~1. All abstracts of conviction received by the Department shall be indexed, compiled, and recorded on the Department's computer in a manner that will allow retrieval and disclosure of the information required by A.R.S. § 28-1061(B), (C), or (D) to be reported on abstracts of conviction.~~

~~2. All reports of conviction received by the Department pursuant to Chapter 10, Title 28, Arizona Revised Statutes, shall also be indexed, compiled, and recorded on the Department's computer in a manner that will allow retrieval and disclosure of the information required to be reported to the Department pursuant to Article III thereof.~~

~~**C.** Disposal of applications, notice of change of address and abstracts of conviction. When the information on the documents referred to in subsections (A) and (B) of this rule has been stored on the Department's computer, they shall be stored in a manner which will allow retrieval as needed by the Department or court order and destroyed in accordance with records destruction schedules established by this Department and the Department of Library, Archives & Public Records.~~

NOTICE OF FINAL RULEMAKING

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION TITLE, REGISTRATION, AND DRIVER LICENSES

PREAMBLE

1. Sections Affected: **Rulemaking Action:**

R17-4-704 Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. §§ 28-366 and 28-907(B)

Implementing statute: A.R.S. § 28-907(B)

3. The effective date of the rules:

August 10, 2001

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 1488, April 6, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 1710, April 27, 2001

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Bill Bishop, Rules Analyst

Address: Arizona Department of Transportation
Administrative Rules Unit, Mail Drop 507M
3737 N. Seventh Street, Suite 160
Phoenix, Arizona 85014-5017

Telephone: (602) 712-8449

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E-mail: bjbishop@dot.state.az.us

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters: www.dot.state.az.us/about/rules

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The Department reviewed R17-4-704 as it committed to do in a five-year rule review report approved by the Governor's Regulatory Review Council on December 7, 1999 (F-99-1202). A.R.S. § 28-907(B) requires the Department to adopt standards in accordance with 49 CFR 571.213, the Federal Motor Vehicle Safety Standard for child restraints. 49 USC § 30103 requires that the states can only adopt a standard that is identical to the federal standard. This rulemaking will amend R17-4-704 to incorporate the current federal standard by reference.

7. A reference to any study that the agency relied on its evaluation or justification for the rule, and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

A.R.S. § 28-907 provides that when the Department adopts the federal standard by rule, the standard is then enforceable by the Department of Public Safety and violators are subject to a fine. The fines are placed in a fund that is used to buy child seats for the use of Arizonans that cannot afford them. This benefits the public and businesses that sell child restraint systems. This rulemaking will also make it clear that only the federal standard applies and not separate federal and Arizona standards. The consumer market for child-restraint systems is also governed by the federal standard and so consumers should feel little impact. The rulemaking will impose costs on state agencies for rule development and regulatory review.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

No changes have been made to the proposed rules.

11. A summary of the principal comments and the agency response to them:

The Department received no comments about this rulemaking.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

49 CFR 571.213 (October 1, 2000) is incorporated by reference in the one and only subsection in this rulemaking.

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION TITLE, REGISTRATION, AND DRIVER LICENSES

ARTICLE 7. MISCELLANEOUS RULES

Section

R17-4-704. ~~Child-restraint systems in motor vehicles~~ Child-restraint Systems in Motor Vehicles

ARTICLE 7. MISCELLANEOUS RULES

R17-4-704. ~~Child-restraint systems in motor vehicles~~ Child-restraint Systems in Motor Vehicles

Child-restraint systems shall ~~be constructed to specifications contained in~~ comply with 49 CFR 571.213, Federal Motor Vehicle Safety Standard number 213. 49 CFR 571.213, revised October 1, 2000, is incorporated by reference and on file with the Arizona Department of Transportation and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments. ~~Safety Standard 213 requires the following information be provided with the restraint system.~~

1. ~~On a permanent label attached to the restraint, the statement "This child restraint system conforms to all applicable federal motor vehicle safety standards".~~
2. ~~On a permanent label, attached to the restraint, the manufacturers recommendations for the minimum and/or maximum weight and height of the children who can safely occupy the system.~~
3. ~~Printed installation instructions with step-by-step procedures, including diagrams for installing the system in motor vehicles, positioning the child in the system, and adjusting the system to fit the child. Each restraint system shall have a location on the restraint for storing the manufacturers installation instructions.~~

~~A copy of Federal Motor Vehicle Safety Standard 213 is on file with the Office of the Secretary of State.~~